

EXHIBIT 514

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 -----X

5 IN RE: NATIONAL PRESCRIPTION MDL No. 2804
6 OPIATE LITIGATION,

Case No. 17-MD-2804

6 This document relates to:

7 All Cases Hon. Dan A. Polster

8 -----X

9
10 * * HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER * *

11 * * CONFIDENTIALITY REVIEW * *

12 VIDEOTAPED DEPOSITION

13 OF

14 THOMAS P. NAPOLI

15 New York, New York

16 Thursday, January 17, 2019

17

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19

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21

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Reported by:

23 ANNETTE ARLEQUIN, CCR, RPR, CRR, RSA

24

1 A. Yup.

2 Q. All right.

3 A. So it's just another source of
4 intelligence to help us be more effective in
5 compliance.

6 Q. All right. You can set this document
7 aside. I'll hand you what we'll mark as
8 Exhibit 25.

9 (Napoli Exhibit 25, Actavis document
10 entitled "Project Continuation
11 Justification: SOM Statistical Model
12 Development and Hosting 'in the Cloud'",
13 Bates-stamped ALLERGAN_MDL_ 03535253
14 through 257, marked for identification, as
15 of this date.)

16 BY MR. EGLER:

17 Q. Mr. Napoli, can you look at
18 Exhibit 25, and like the other ones today the
19 first one has no Bates numbers and then the
20 second page is ALLERGAN_MDL_03535253 through
21 257.

22 And when you're ready, can you tell
23 me if you've ever seen this document before.

24 (Document review.)

1 A. I have seen this document.

2 Q. Did you write this document?

3 A. Yes, sir.

4 Q. Why did you write this document?

5 A. I wrote this document as a means to
6 get the Cegedim or Cegedim-Dendrite solution
7 implemented.

8 Q. At the bottom left-hand corner of the
9 first Bates-stamped page, 253, it has the date
10 February 19th, 2015.

11 A. Yes.

12 Q. Do you remember writing this document
13 around that time?

14 A. It's very likely.

15 Q. Then on the second Bates-stamped
16 page, 254, the section that starts with:
17 "Background."

18 Do you see that?

19 A. Yes.

20 Q. The second full text paragraph, I'm
21 just going to start reading it into the record.
22 It says, "Based on this compliance need, Cegedim
23 did in fact develop and deliver a SOM
24 statistical model to be incorporated into our

1 order management system within SAP. Due to
2 successive acquisition activities since product
3 initiation the implementation has been placed on
4 hold at several junctures based on business
5 integration needs. During the past several
6 years, DEA has become more aggressive in its
7 approach related to SOM/Know Your Customer
8 taking against" -- "taking action against a
9 growing number of companies for having
10 non-compliant SOM programs. In an effort to
11 ensure compliance with the regulations, both the
12 C/S compliance, order management teams, have
13 collaborated making efforts to enhance
14 compliance from customer vetting, order
15 review/evaluation through
16 investigation/disposition.

17 "This manual effort is very labor
18 intensive, as the current system was not
19 configured with any analytical tools to support
20 timely and accurate decision making. This
21 approach also introduces the element of human
22 interaction into the order evaluation process.

23 "Additionally, the current process
24 can have an impact on the amount of time

1 required to release a pending order that is under
2 review, affecting customer service/fill rate
3 levels."

4 Do you see that there?

5 A. I do.

6 Q. Did you write that?

7 A. Yes, I did.

8 Q. At the time that you wrote it, did
9 you believe what you wrote there?

10 MR. LUXTON: Objection to form.

11 A. Yup, I do believe that those facts
12 are accurate. We did have -- we did have a
13 compliance system, but we wanted to enhance our
14 compliance to ensure that we were always
15 continually evolving it on the high ground.

16 Q. So above there you write, under
17 background, "The SOM" -- "The SOM automation
18 project initially commenced in 2011 with the
19 primary goal of replacing our, quote, threshold,
20 unquote, based system with the CFR compliant
21 model developed by Cegedim. This project was
22 initiated in an effort to ensure compliance with
23 the Code of Federal Regulations, SOM
24 requirements, controlled substances, 21 CFR

1 1301.74 b, as well as December 2007, DEA
2 memory."

3 Do you see that?

4 A. I did.

5 Q. When you wrote that in February 2015,
6 did you believe that to be true?

7 A. I did believe that Buzzeo had a
8 system that they were proposing that was
9 compliant with the CFR

10 We also had one as well, but we
11 wanted to move up to a more enhanced
12 sophisticated system.

13 Q. So other parts of the -- this memo
14 talk about a suspicious order monitor --
15 suspicious order monitor statistical model that
16 will be hosted, quote, in the cloud and based on
17 Actavis's order data.

18 A. Yes.

19 Q. Do you remember whether this
20 cloud-based SOM statistical model was ever
21 adopted at Actavis?

22 A. This system was created. We used it
23 in a test environment. We're happy with it. We
24 were subsequently acquired by Teva and it was

1 put on hold and I don't believe that Teva chose
2 to utilize it.

3 Q. All right. So with regard to the --
4 this is -- so with regard to your
5 understanding -- well, with regard to your
6 understanding, Actavis never implemented the
7 cloud-based system that's discussed in this
8 memo; is that right?

9 A. That's correct. When Teva acquired
10 Actavis around this time frame they already had
11 their own program in place for Suspicious Order
12 Monitoring.

13 Q. So this goes to the number of
14 corporate transactions that took place --

15 A. Right, right.

16 Q. You're describing the company as
17 being bought by Teva. Part of what was Actavis,
18 was purchased and closed on by Allergan.

19 Do you have an understanding of that
20 as well or some type of transaction occurred
21 between Allergan and Actavis; is that right?

22 A. Right.

23 Q. Either Actavis bought Allergan or
24 Allergan bought Actavis?

1 A. Actavis bought Allergan.

2 Q. All right. And as far as you're
3 concerned -- well, during that process, when did
4 you leave?

5 A. I left around maybe October of 2016.
6 Sometime in the early fall of 2016.

7 Q. So I'm going to hand you what we will
8 mark as Exhibit 26.

9 A. Okay.

10 (Napoli Exhibit 26, Email chain
11 beginning with email dated 1/11/16 from
12 Baran to Russo with attachment,
13 Bates-stamped ALLERGAN_MDL_ 03431731
14 through 1739, marked for identification, as
15 of this date.)

16 BY MR. EGLER:

17 Q. Before we get to Exhibit 26, why did
18 you leave?

19 A. I was laid off.

20 Q. All right.

21 A. Because Teva already had a DEA
22 compliance staff and program. I helped them
23 orient them with -- with our side of the
24 business and was part of a reduction in force.

1 Q. All right. So looking at what I
2 marked as Exhibit 26, can you page through it.
3 I'll read into the record. It's
4 ALLERGAN_MDL_03431731 through 1739.

5 If you look through this generally,
6 but I'm just going to ask you a few questions
7 about this.

8 (Document review.)

9 Q. Now I'll note for the record that the
10 last email that you're on the page appears on
11 the third page of this document, as I read it.

12 A. Um-hmm.

13 (Document review.)

14 A. Okay.

15 Q. All right. Based on the emails that
16 are here, do you remember around August 2015
17 Actavis deciding to sell to Bell Medical again?

18 MR. KNAPP: Objection to form.

19 A. I do recall this series of emails and
20 this situation.

21 Q. All right. Did you have any input in
22 the decision whether to start selling controlled
23 substances to Bell Medical around this time?

24 A. My input would have been from a DEA

1 compliance standpoint the -- you can see in this
2 email string that there was -- both of our
3 auditor investigators did a lot of due diligence
4 on this and also met personally, I believe, with
5 the individual from Bell Medical, in Marlboro,
6 New Jersey.

7 And the reason why this stands out to
8 me is that, you know, Actavis, we had a model
9 where we did not distribute direct to dispensing
10 physicians. And in this case it was a case
11 where we wanted to make sure that we did the
12 right amount of due diligence and understand and
13 monitor what the product -- it would only be one
14 product, what the quantities would be, and they
15 were for these clinics -- Buprenorphine -- they
16 were for clinics to assist, I believe, addicts
17 with -- Buprenorphine was used for more -- for
18 heroin, I think.

19 Q. Did you ever do a site visit to the
20 Bell Medical facility?

21 A. I didn't, but I believe Will Simmons
22 may have.

23 Q. Did you ever talk with him about the
24 site visit that he did?

1 A. I don't have a distinction
2 recollection of it.

3 Q. All right. So now we have a couple
4 of exhibits that are out of order time-wise.

5 A. Okay.

6 Q. The first one we'll mark as
7 Exhibit 27.

8 (Napoli Exhibit 27, Email dated
9 11/13/13 from Kemnitzer to distribution
10 list, Bates-stamped PPLPC020000735777
11 through 782, marked for identification, as
12 of this date.)

13 MR. LUXTON: Thanks.

14 BY MR. EGLER:

15 Q. Mr. Napoli, can you look at
16 Exhibit 27. I'll note for the record, again,
17 it's not an Actavis or Allergan document. It's
18 noted as PPLPC020000735777 through 782. The
19 last page is marked as nonresponsive.

20 Can you look at this document and
21 tell me if you ever remember receiving an email
22 like this in November 2013.

23 (Document review.)

24 A. I don't have an exact recollection of

1 this. This looks like an agenda for a New
2 Jersey Pharmaceutical Industry Group meeting.

3 Q. All right. So if you turn to the
4 third page of this document, which is 5779 --

5 A. Yes.

6 Q. -- there is an email from Michael
7 Meggiolaro. It's M-e-g-g-i-o-l-a-r-o.

8 A. Good job.

9 Q. It's dated Thursday, November 7,
10 2013, at 5:09 p.m.

11 Do you see that there?

12 A. I do.

13 Q. And he writes, apparently to a person
14 named Lisa Butler. "Lisa, you are so good. I
15 promised the update for all the topics yesterday
16 but didn't get to them. Here is what I had
17 received. You already added Susan Carr's, so I
18 don't have to add hers to the list."

19 And just to note, your name appears
20 on that email; is that right?

21 A. Yes.

22 Q. And it says, "Please update the
23 agenda accordingly at 2014 quota letters" -- and
24 then number two is, "SOM programs."